


Exhibit V

 KeyCite Yellow Flag - Negative Treatment
Distinguished by [Austin v. Nestle USA, Inc.](#), D.S.C., October 28, 2010

2009 WL 2842745

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United States District Court, D. South Carolina.

In re: NEW YORK RENU WITH MOISTURELOC
PRODUCT LIABILITY LITIGATION

This Document Applies to [All Cases](#)

In re: Bausch & Lomb Contact Lens
Solution Product Liability Litigation

This Document Applies to [All Cases](#)

No. 766,000/2007, MDL 1785,
C/A 2:06-MN-7777-DC.

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July 6, 2009.

MEMORANDUM OPINION AND ORDER ON
DOCUMENTS ASSERTED AS PROTECTED BY
ATTORNEY-CLIENT PRIVILEGE OR AS WORK
PRODUCT

CAPRA, J.

*1 In this litigation, Defendant Bausch & Lomb has refused to produce a number of otherwise responsive documents on the ground that they are protected by the attorney-client privilege or the work product doctrine. A previous opinion and order entered in this case (the “May 6, 2008 Opinion and Order”) resolved a number of claims of privilege and work product with respect to a “first wave” of Bausch & Lomb documents.

In the “first wave” both federal and state plaintiffs sought the documents that were claimed to be immune from discovery. In the present ruling, only the New York plaintiffs (“Plaintiffs”) are seeking the documents.

The documents that are subject to this Order have been set forth in exhibits to an affidavit by Robert Bailey, Esq., Vice President and General Counsel for Bausch & Lomb. This discussion and Order follow the exhibit form set forth in the Bailey affidavit, as argued by the parties.


I have reviewed the pertinent case law and the written submissions by the parties. I also heard oral argument on



some of the more difficult legal questions presented by these exhibits. What follows is a short discussion of the pertinent case law, and a justification for the orders. Because there is a need for expedition, the case law discussion is truncated.


The May 6, 2008 Opinion and Order sets forth a number of legal principles that are pertinent to the claims of privilege and work product for the documents currently before me. The parties have not sought reconsideration of these basic legal principles, and so they are set forth here without extensive explication:

1) Defendant, as the party invoking the attorney-client privilege and work product immunity, has the burden of showing that the basic requirements for those protections are met.

2) Intra-corporate communications to counsel may fall within the privilege if the predominant intent is to seek legal advice.

3) Intra-corporate communications to and from counsel can retain a privilege if disclosure is limited to those who have a “need to know” the advice of counsel; the company’s burden “is to show that it limited its dissemination of the documents in keeping with their asserted confidentiality, not to justify each determination that a particular employee should have access to the information therein.”  [Federal Trade Comm’n v. GlaxoSmithKline](#), 294 F.3d 141, 147–48 (D.C. Cir.2002).

4) Privilege claims are controlled by New York law, although the law on attorney-client privilege is virtually the same as federal common law. *See, e.g.*,  [NXIVM Corp. v. O’Hara](#), 241 F.R.D. 109, 124 (N.D.N.Y.2007) (“the distinction between New York and federal law on attorney-client privilege is quite indistinguishable, as the law interseets in all of its facts, and are viewed interchangeably”);  [Bank of Am., N.A. v. Terra Nova Ins. Co. Ltd.](#), 211 F.Supp.2d 493 (S.D.N.Y.2002) (“New York law governing attorney-client privilege is generally similar to accepted federal doctrine.”). With respect to privilege, the New York Court of Appeals uses a utilitarian analysis, to provide protection to communications to and from counsel that would not be made in absence of the privilege. *See generally* Martin & Capra, New York Evidence Handbook § 5.2 (2d ed.2003).

*2 5) When a consultant is part of attorney-client communications, the privilege is retained only if the consultant's services are necessary to the legal representation.  *United States v. Kovel*, 296 F.2d 918, 921 (2d Cir.1961). The services of a public relations consultant are not necessary to the legal representation. *Haugh v. Schroder Inv. Mgmt. North Am. Inc.*, 2003 U.S. Dist. LEXIS 14586 at *8 (S.D.N.Y.2003).

6) If a report is being prepared for ultimate public disclosure, the drafts of that report are protected by the attorney-client privilege only to the following extent: if the draft is sent to the lawyer for a legal-advice review, then those statements that are not ultimately revealed to the public are privileged. *Schenet v. Anderson*, 687 F.Supp. 1280, 1282–4 (E.D.Mich.1988).

These legal principles solve many of the issues presented, but not all. Defendant has interposed a number of claims of work product protection, and these claims raise legal issues that were not presented by the first wave of documents. For their part, New York Plaintiffs point out (correctly, as will be seen below), that the work product protection under New York law is narrower than that provided by federal law. With this framework of new issues presented, I proceed to the challenged exhibits.

Exhibit 1 (BL000008073–BL000008085)


This is a report prepared for Bausch & Lomb by Panzica Consulting. Panzica conducted an audit of the Greenville facility after an FDA inspection had found a number of inspection violations. Panzica has extensive experience in assisting companies in complying with FDA standards. Outside counsel for Defendant retained Panzica after the FDA report and warning letter were issued; at that time, it was certainly foreseeable that lawsuits might be brought by the FDA and by Bausch & Lomb consumers as well. ¹

Defendant claims that the Panzica report is protected by the attorney-client privilege and as work product. Those claims are discussed in order.

Attorney–Client Privilege:


The Panzica report was a communication to counsel; there is no indication that it was circulated widely within the corporation, i.e., to personnel who had no “need to know.” New York Plaintiffs’ argument on privilege seems to be that

the report is not privileged because Panzica was not an agent necessary to the legal representation under *Kovel*. ² As previously noted, I have held that communications among attorney, client and public relations agent are not within the privilege because a public relations agent is not necessary to the legal representation. But of course the previous holding does not mean that communications with consultants can never come within the privilege. It depends on what the consultant is hired to do. The test is whether their function is necessary for the lawyer's representation to be effective.

I find that Panzica's services were necessary to the legal representation under *Kovel*—although I acknowledge that there appears to be no case law specifically on whether regulatory consulting falls with the *Kovel* doctrine. ³ Panzica is an expert in compliance with FDA technical and regulatory standards—an area that lawyers cannot be expected to master in the ordinary course of legal work. An expert's help was certainly necessary to assist the lawyers in understanding how to get the company to comply with technical standards and thereby prepare for not only regulatory action, but also for any claims by individuals based in part on the failure to comply with those regulatory standards. It is also relevant that Panzica was retained by outside counsel; under *Kovel*, retention by counsel rather than the client cuts in favor of a finding that the agent was necessary to the representation—and rightly so, because retention by the lawyer is an implicit conclusion of the lawyer that the consultant's expertise will maximize the lawyer's services. See  *Cavallero v. United States*, 284 F.3d 236, 247 (1st Cir.2002) (“Whether Hale and Dorr, as opposed to the Cavallaros or their sons, hired Ernst & Young is, as the district court recognized, probative when considering whether Ernst & Young was employed to help Hale and Dorr render legal advice. Typically, agents of an attorney are retained by or at the discretion of the attorney and under the attorney's supervision.”) (citation omitted).

*3 But even though Panzica's services were necessary to the legal representation, this does not mean that Panzica's report is privileged in its entirety. The privilege only covers confidential communications among Panzica, corporate personnel, and the lawyers. My review of the report indicates that it is made up in large part of factual findings based on a view of conditions, drawings, etc. at the Greenville plant. The attorney-client privilege does not protect these underlying facts. Assume that a lawyer for the corporation had inspected the plant, viewed pertinent drawings, etc., and came to conclusions about the plant's condition and the possible

need to remediate. It's clear that what the lawyer found would not be privileged (and neither would the lawyer's opinion) because it was not based on communications from the client. The situation cannot be improved by sending an agent out to get the very same information.

A case in point is  *U.S. Postal Service v. Phelps Dodge Refining Corp.*, 852 F.Supp. 156 (E.D.N.Y.1994). The Post Office bought property from the defendant and then sued, alleging that the defendant had failed to remove toxic waste from the property. The defendant hired expert consultants to conduct soil studies. The consultants conducted an investigation of the soil and reported back to the corporation and counsel, Magistrate Judge Go was skeptical that these consultants were necessary to the legal representation under the circumstances of that case (most importantly because the consultants were hired by the corporation, not by the lawyer); but even if the consultants were necessary to the legal representation, Judge Go held that the consultants' opinions and conclusions were not privileged:

Moreover, these consultants based their opinions on factual and scientific evidence they generated through studies and collected through observation of the physical condition of the Property, information that did not come through client confidences. Such underlying factual data can never be protected by the attorney-client privilege and neither can the resulting opinions and recommendations.



 852 F.Supp. at 161.


I find, therefore, that the Panzica report is privileged only to the extent that the findings in the report are derived from confidential communications made by corporate employees to Panzica. Initially, Defendant argued that the entire report was privileged but this is demonstrably not so. For example, in one part of the report, Panzica reviews laboratory data sheets. These are pre-existing documents, not communications to Panzica or counsel, and so they are not covered by the privilege. In another part Panzica reviews drawings and comes to a conclusion. And so forth. On the other hand, some of Panzica's facts and conclusions are


clearly based on discussions with personnel at the plant, and those facts and conclusions would be privileged under the foregoing analysis.





I gave Defendant the opportunity to redact the Panzica report for conclusions that are based in whole or part on confidential communications from Bausch & Lomb personnel. In response, Defendant submitted the report with proposed redactions. I reviewed the redactions and have determined that they are appropriate, as the information redacted is, more likely than not, derived from confidential communications provided by corporate personnel to Panzica. I therefore order the Panzica report to be produced to Plaintiffs as redacted.

Work Product:


*4 The Panzica report is not protected as work product under New York law, Under  CPLR 3101(d)(2), a report is qualifiedly immune from discovery only if it was prepared *solely* in anticipation of litigation. See Siegel, *New York Practice* at 501 (noting the “commonly recognized” principle that in order to qualify for protection under CPLR 31301(d), “the item must have been prepared exclusively for litigation”); *Agovino v. Taco Bell*, 225 A.D.2d 569, 639 N.Y.S.2d 111 (2d Dept.1996). The Panzica report is designed not only to prepare for litigation but also to suggest measures for improved procedures for the future. Suggestions for future improvement are strewn throughout the report. Under these circumstances, Defendant has not satisfied its burden of proving that Panzica prepared the report solely in anticipation of litigation. See McKinney's Practice Commentaries to CPLR 3130, at C3101:37 (party seeking protection under  CPLR 3101(d)(2) has the burden of proving that it was prepared solely in anticipation of litigation).






Defendant cites a number of cases in support of its position that the Panzica report is protected as work product. But none are on point. The cases finding similar reports work product under federal law are not persuasive, because the federal law on work product protects a report prepared “because of” litigation. See  *In re Grand Jury Subpoena (Mark Torf/Torf Entertainment Mgmt.*, 357 F.3d 900 (9th Cir.2004). Under the federal test for work product, a report prepared for more than one purpose can be protected so long as litigation is one causative purpose. Thus the *Torf* case relied upon by Defendant specifically notes that the report, while made for “dual purposes,” is nonetheless protected by the federal work

product doctrine.⁴ But, as seen above, “dual purpose” reports are not protected by  CPLR 3101(d)(2).

Defendant relies upon not only  CPLR 3101(d), but also  CPLR 3101(c), which provides absolute protection for the “work product of an attorney.” Defendant cites cases such as *Santariga v. McCann*, 161 A.D.2d 320, 555 N.Y.S.2d 309 (1st Dept.1990), for the proposition that the absolute work product protection covers the work of consultants as well as lawyers. This may be so, but CPLR 31301(c), even as extended by *Santariga*, is of no help to Defendant. According to Siegel,  CPLR 3101(c) is essentially an anomaly. It cannot mean what it says, because applied literally it would provide absolute protection for a “will, contract, mortgage, or the like”—as these are all a lawyer's work product. Siegel notes that the New York courts have recognized that  CPLR 3101(c) is an anomaly and have therefore

cast precious little under the “work product” category of subdivision (c), preferring instead to fit doubtful items under the ... banner of subdivision (d)(2), where the immunity can be withdrawn and the matters ordered disclosed when stated conditions are met. It has been held that an item will not even begin to qualify as “work product” merely upon a showing that a lawyer drew it or did it; it must be something that only a lawyer could do. The fact that a lawyer has taken a statement from a witness, for example, does not transmute the statement into a “work product”: a lay person could have taken it. The general rule is that data received by the attorney from others while investigating in behalf of the client is [not] “work product” under subdivision (c). This is so even though the material itself, such as a statement or report, may qualify as prepared in anticipation of litigation” and thus be immunized by subdivision (d)(2).

*5 Siegel, New York Practice at 498. See also Weinstein, Korn & Miller, New York Practice ¶ 3101.44 (“ CPLR 3101(c) should be construed as narrowly as possible to include only those materials prepared by the attorney, acting as an attorney, and containing his analysis and trial strategy.”).

Most importantly, even if  CPLR 3101(c) protects reports prepared by consultants, this will only be so if the report is prepared *solely* in anticipation of litigation—and, as stated above, Defendant has not established its burden of showing that the Panzica report was prepared solely for litigation. See Weinstein, Korn & Miller, *New York Civil Practice* ¶ 3101.50 (records prepared in the regular course of business “are not protected by either  CPLR 3101(c) or  CPLR 3101(d) because they are, in general, not prepared *solely* for the purpose of litigation.” (Emphasis added).⁵ It would be odd indeed if the single purpose limitation of  CPLR 3101(d) did not apply to the more absolute protection provided by  CPLR 3101(c). Why would the legislature intend that the broader protection could be more easily invoked than the narrower one?

Privilege claim sustained in part and denied in part. Work product claim denied.

Exhibit 2 (BL106095385–BL106095388)

Exhibit 2 is an email string that begins with a discussion about Bausch & Lomb's response to an inquiry from a Spanish newspaper, El Mundo, regarding a speech made by Dr. Donald Tan, an ophthalmologist who discussed the alleged association between Renu with Moistureloc and *keratitis*. The first email, dated June 15, 2006, is from an employee of Biss Lancaster, a public relations firm, hired by Bausch & Lomb to prepare external communications regarding the fusarium investigation in Europe. It contains a proposed statement to the press regarding the Tan speech. Defendant has redacted part of the proposed statement on grounds of privilege. That privilege claim must be denied. As discussed in the May 6, 2008 Opinion and Order, communications that include a public relations firm are not privileged because the public relations firm is not necessary to the legal representation. I note also that Biss Lancaster was hired by Bausch & Lomb, not its lawyers, and the email is not sent to corporate or outside counsel. Accordingly, the email from Biss Lancaster on BL106095388 must be produced in unredacted form.

There are two more redactions that are further up the email string. These redactions are appropriate because: 1) the writers have included, and are directly requesting advice from, Bob Bailey, General Counsel for Bausch & Lomb; 2) no Biss Lancaster representatives are parties to these emails. While the public relations consultant *started* the email string, this does not make the entire string unprivileged. If a client consults in confidence with a lawyer about the legal aspects of a public relations problem raised by a p.r. consultant, and the consultant is not part of that conversation, then those client-lawyer communications are protected by the privilege.

**6 Privilege claim sustained in part and denied in part.*

Exhibit 3 (BL105109461–105109462)

This is an email string in response to statements from two doctors who “began researching the bicompatibility of multipurpose contact solutions with different types of contact lenses.”⁶ These doctors published a grid on a website “showing the ReNu product to be incompatible with almost all SiHy lenses.”⁷ The personnel on the email are considering a rebuttal to the findings on the website. Bob Bailey is included on the emails. Defendant redacts, on privilege grounds, a communication from Jeffrey Nardoci of the marketing division of Bausch & Lomb. The redacted communication seeks legal advice from Bailey. All corporate personnel on the email have a “need to know” and therefore communications to them are within the privilege.

Dr. Chris Snyder, a consultant, is also included on the redacted email. Dr. Snyder is a professor of optometry who is an expert on corneal staining.⁸ I find that Dr. Snyder was necessary to the legal representation under *Kovel* and therefore his inclusion on the email did not cause the privilege to be lost. Dr. Snyder was hired to provide the technical expertise and support that Bailey would need to frame a proper legal response to the medical data and conclusions that were posted on the website.

Privilege claim sustained.

Exhibit 4 (BL106686177–BL106686179)

This is a draft chart prepared by Quantic Group. Quantic is a consulting firm that was retained by outside counsel for Bausch & Lomb, after an FDA investigation of the Greenville plant resulted in an FDA–483 report listing 18 observations

—and after lawsuits were brought by users of ReNu with Moistureloc. Quantic is “a group of consultants who have scientific and technical expertise, as well as experience in FDA enforcement actions, including the audit/inspection process, the issuance and response to FDA–483 observations, and the issuance and response to warning letters and other enforcement actions available to FDA.”⁹

The chart attempts to provide an explanation of why the reports of *Fusarium keratitis* were most closely associated with Renu with Moistureloc and not another Bausch & Lomb product. Defendant claims that the chart is protected under the attorney-client privilege and the work product immunity. These claims are discussed in turn.



Attorney–Client Privilege:

Plaintiffs claim that the chart is not privileged because Quantic was a consultant—like the public relations consultants discussed in the May 6, 2008 Opinion and Order, whose inclusion in corporate-attorney communications resulted in a loss of the privilege. But Quantic's role is clearly distinguishable from the role performed by a public relations consultant. Quantic provided expertise about the regulatory process and Bausch & Lomb's possible exposure to enforcement proceedings by the FDA—as well as anticipated lawsuits brought by individuals who would be likely to rely on adverse FDA determinations as part of their case. Thus, I find that Quantic was necessary to the legal representation under *Kovel*—a finding supported in part by the fact that Quantic was retained by outside counsel for Bausch & Lomb. As discussed above, courts have found retention by the lawyer, as opposed to the client, relevant in determining whether the consultant was necessary to the legal representation.

 *Cavallero v. United States*, 284 F.3d 236, 247 (1st Cir.2002).


**7* I note that the chart is labelled “draft.” But this chart does not raise the same problem of draft presentations considered in the May 6, 2008 Opinion and Order. Those were draft powerpoints of a presentation that was going to be made to the FDA—so the final report was always intended for public disclosure. In contrast, the Quantic chart was never intended to be released to the public. It was released only to those within the corporation that needed to know its contents. For all these reasons, the Quantic chart, Exhibit 4, is protected by the attorney-client privilege.

Work Product:


Because I find the chart protected by the attorney-client privilege, there is no need to determine whether it is also protected material prepared in anticipation of litigation under  CPLR 3101(d). It should be noted, however, that the work product question is later taken up in detail with respect to other Quantic reports that are not completely protected by the attorney-client privilege. As will be seen, I find that those reports fall within the protections of  CPLR 3101(d), and that Plaintiffs have not made a showing of necessity that would overcome the qualified immunity. The work product analysis, as applied to those documents, should be equally applicable to Exhibit 4.

Privilege claim sustained. Work product claim deferred.

Exhibit 5 (BL120849169 BL120849170–BL120849180 BL120843003)

These are emails and an attachment involving Quantic's work in response to the FDA's inspection at the Greenville plant. The emails—from a Quantic employee to several Bausch & Lomb personnel responsible for quality control and compliance—simply indicate that an attachment is being sent. A mere referral of a document, without any indication of the content of that document, is not privileged, because the mere fact of a communication is distinguishable from the underlying, confidential content of the communication. See  *U.S. Postal Service v. Phelps Dodge Refining Corp.*, 852 F.Supp. 156, 163 (E.D.N.Y.1994) (“Examples of documents from an employee to house counsel which are not privileged include document 4, which is merely a transmittal letter ...”). See also *Hoopes v. Carota*, 74 N.Y.2d 716, 544 N.Y.S.2d 808 (1989) (mere fact of consultation is not privileged). Nor is the mere referral of a document work product, because the referral itself—independently of what is referred—is not material prepared in anticipation of litigation. It's just a referral.

The attachment to the email is a different matter. The attachment is a chart that takes the FDA inspection point by point and provides responses and suggestions for compliance. It is not prepared for ultimate public disclosure—rather it appears to be directed internally, prepared by Quantic personnel and sent to those with a need to know the statements and suggestions set forth. It is true that the chart was prepared by Quantic, and Quantic is not the lawyer. But as discussed above, Quantic was necessary to the legal representation,

because its work on technical and regulatory matters was designed to assist outside counsel in protecting Bausch & Lomb's legal position with respect to the FDA and private claimants. That means Quantic was part of the attorney-client relationship, and therefore any confidential communications from Quantic representatives to Bausch & Lomb personnel with a “need to know” are protected by the attorney-client privilege. The attorney does not need to be a direct part of such conversations because Quantic is a necessary agent of the attorney. See  *United States v. Kovel*, 296 F.2d 918, 921 (2d Cir.1961) (confidential communications between client and a necessary agent of the attorney are protected by the privilege even though attorney is not present).¹⁰

*8 Accordingly, the transmittal emails must be produced in unredacted form. But the attachment is protected by the attorney-client privilege.


Privilege claim denied as to emails and sustained as to attachment. Work product claim denied as to emails and deferred as to attachment.

Exhibit 6 (BL12851477–BL120851478 BL120851511–BL120851515)


This is an email string involving discussions about the possibility of retaining Quantie for further work involving the Greenville plant, after Quantie's initial work in response to the FDA investigation. This proposed work would be addressed to other potential problems that, under the circumstances, could give rise to claims in litigation brought by the FDA or private plaintiffs. The email string begins with a proposal from Quantie to David Hanlon, Director of Global Quality Assurance for Moistureloc. Hanlon then refers it, together with his comments, to Bausch & Lomb personnel as well as to outside counsel. The string continues with various discussions about whether and how to proceed.

Defendant claims that the entire string is protected by the attorney-client privilege and the work product doctrine. I find as follows:

1. The first emails, dated 7/18/2006 and dated 8/11/2006, discuss whether and how to implement the Quantic proposal. They are routed to a lawyer and are privileged, as the decision that is to be reached was clearly relevant to Bausch & Lomb's legal position. Everyone on the email would have a need to know the communications.

2. The next two emails, from Tom Eggleton and David Hanlon, both sent on 8/14/2006, do not include counsel, but they in large part reflect legal advice that has been received. See, e.g.,  *Santrade, LTD. v. General Electric Co.*, 150 F.R.D. 539, 543 (E.D.N.C.1993) (information subject to the privilege “may be transmitted between non-attorneys (especially individuals involved in corporate decision-making) so that the corporation may be properly informed of legal advice and act appropriately”). It is true that some of the statements in these emails do not refer to legal advice, but redaction is not an option: if the legal advice is redacted, the remaining statements make no sense. The New York Court of Appeals has stated that

the privilege is not narrowly confined to the repetition of confidences that were supplied to the lawyer by the client. That cramped view of the attorney-client privilege is at odds with the underlying policy of encouraging open communication; it poses inordinate practical difficulties in making surgical separations so as not to risk revealing client confidences; and it denies that an attorney can have any role in fact-gathering incident to the rendition of legal advice and services.

 *Spectrum Systems Intern, Corp. v. Chemical Bank* 78 N.Y.2d 371, 379, 575 N.Y.S.2d 809, 814–15 (1991).

Accordingly, I find that the 8/14/2006 emails from Eggleton and Hanlon are privileged in their entirety.

3. The next email, from Lisa Tinsley dated 8/14/2006, provides a “point of clarification” to the discussion, and attaches a report of an investigation. This email is not privileged. It does not refer to or implement legal advice, it simply clarifies a point of prior practice and refers to a couple of prior reports. The email is not sent to counsel. The reports it refers to were not prepared by Quantec nor any other consultant hired by a lawyer.¹¹ And production of this email will not disclose any legal advice that had been received to that point.

*9 4. The next email, from David Hanlon, dated 8/14/2006, is protected by the attorney-client privilege, because it specifically refers to counsel's opinion about a legal position, and its argument is dependent on legal advice. The privilege applies even though a lawyer is not included in the email—implementation of legal advice within the corporate structure, by communicating that advice to those with a need to know, is privileged. See *Santrade*, supra. See also *Spectrum*, supra.

5. The next email, from Rao Gurijala, dated 8/15/2006, is privileged in part. Specifically, the first sentence may be redacted because it would implicitly disclose the content of some of the protected emails that went before. The rest of the email is not privileged, however. There are no lawyers included, and the remainder of the email generally mulls over a question of corporate policy.

6. The final email in the string, from David Hanlon, dated 8/18/2006, is not protected by the privilege. Again no lawyers are involved; no legal advice is explicitly or implicitly raised. The email is severable from what has gone before.

7. Because the privilege claims are denied in part, it remains to determine whether any statements unprotected by privilege are nonetheless protected as work product. I find that nothing in the email string is protected as work product. Clearly, Tinsley's email is not work product as it is simply a statement about a previous event that was unrelated to litigation. More broadly, the entirety of the email string is a discussion, at least in part, of corporate policy and future business practices; therefore Defendant has not met its burden of proving that the statements unprotected by privilege were prepared solely in anticipation of litigation.

Privilege claims sustained in part and denied in part. Work product claims denied.

Exhibit 7 (BL120849126)

Exhibit 7 is an email from a Quantec consultant, Danny Lenz, to David Hanlon and two Sidley Austin attorneys. The context of the email is that the FDA inspected the Clearwater plant and issued a report listing four inspection observations; Sidley Austin retained Quantec to assist in a response to this new investigation by the FDA. The email is in preparation for Quantec's work on the project.


Two paragraphs of the email are redacted for privilege and work product. I find that the first deleted paragraph—the second paragraph in the email—is neither privileged nor work

product. It is simply a request from Lenz for information about pre-existing documents. Therefore this paragraph must be produced in unredacted form.

The second deleted paragraph—the third paragraph in the email—is properly redacted for privilege as it seeks legal advice, directly from the lawyers, about the scope of Quantic's representation in response to the legal problems raised by the FDA inspection.¹²

Privilege claims sustained in part and denied in part. Work product claims denied in part and deferred in part.

Exhibit 8 (BL120849127–BL120849128)

*10 This exhibit is two emails, the first from Owen Richards of Quantic to David Hanlon, Steven Haight (Vice President of Global Quality Assurance), and a lawyer at Sidley Austin, with copies to Quantic consultants. The second is from David Hanlon, sending along the first email to Lisa Tinsley and Tom Eggleton (both with a need to know), and providing some commentary about Quantic's work. As with Exhibit 7, the topic is Quantic's work in response to the FDA inspection of the Clearwater plant. The first email is entirely redacted, and the second has a small redaction. Defendant relies on privilege and work product. I find these redactions are proper because they involve a discussion about the scope and tenor of a legal response to the FDA inspection—with direct lawyer involvement—and so the redacted material is protected by the privilege. The complete redaction of the first email could perhaps be blue-penciled to allow a clause or phrase to be disclosed, but the New York Court of Appeals has counseled against such an approach.  *Spectrum Systems Intern. Corp. v. Chemical Bank* 78 N.Y.2d 371, 379, 575 N.Y.S.2d 809, 814–15 (1991) (noting the “inordinate practical difficulties in making surgical separations so as not to risk revealing client confidences”). Accordingly, I find the redactions in Exhibit 8 to be justified on grounds of privilege.¹³

Privilege claims sustained. Work product claims deferred.

Exhibit 9 (BL120849111–BL120849113 BL120849118–BL120849120 BL120849121–BL120849124)

These are email strings each involving a redaction of almost the entirety of a single email—from Owen Richards to David Hanlon, with copies to Quantic personnel, Bausch & Lomb personnel, and a Sidley Austin attorney. The email strings involve only those with a need to know—while in three

separate email strings, the email in contention has not been distributed widely. Defendant claims the redacted statement in each email is protected as both privileged and work product.

As with Exhibits 7 and 8, the redacted email involves the scope and tenor of a legal response to the FDA inspection. As previously, Quantic is necessary to the legal representation required to respond effectively to the FDA investigation. And as previously, it might be possible to un-redact a few words or phrases, but it is not appropriate to do so given *Spectrum's* caution against “surgical separations.” I therefore find that the redacted statements are protected under the attorney-client privilege.¹⁴

Privilege claims sustained. Work product claims deferred.

Exhibit 10 (BL123599710)

Exhibits 10–15 all relate to drafts of a report prepared by Bausch & Lomb and counsel, with the assistance of Quantic. Following its investigations of Bausch & Lomb facilities, the FDA requested that Bausch & Lomb prepare a report on any relationship between ReNu with Moistureloc and fusarium *keratitis*. Bausch & lomb submitted a final report—which it refers to as the Fusarium Investigation Summary—to the FDA on July 21, 2006. Attached to the Summary were more detailed reports of the specific tests and research conducted during the Bausch & Lomb inquiry. The final Fusarium Investigation Summary and all its attachments have been produced to Plaintiffs. The controversy is over the drafts of the final report and attachments, as well as emails that served to refer these reports to various people who had a need to know.

*11 Exhibit 10 is an email string of two emails. Defendant claims that the string is protected as privileged and as work product. The string begins with an email to Ronald Fisher, Manager of Global Quality, from Brian David, Manager of R & D Microbiology. Apparently David wanted to send a draft report to Suggy Schrai, a Quantic consultant, for Schrai's review, but he didn't have the email address. So he sent the report to Fisher, and the second email is Fisher's referral of the report to Schrai.

This email string does nothing but refer a report to Suggy Chrai for review—there are no communications in the email other than the referral of the report itself. As previously held, Quantic is a necessary agent for the legal representation. But

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that does not mean that every interaction between Quantic and Bausch & Lomb personnel is privileged, any more than every interaction between a client and an attorney is privileged. As discussed above, both New York and Federal law provide that a mere referral of information to counsel—without any indication of the content of the information—is not privileged. Put another way, the mere fact of contacting counsel and seeking legal advice is not privileged because it does not relate any of the underlying confidential communication. See *Hoopes v. Carota* and *Phelps Dodge, supra*. Nor is the mere fact of a referral anything approaching work product. It is not “material” at all, much less material prepared solely in anticipation of litigation. Accordingly, the email string must be produced to Plaintiffs. The privilege and work product claims with respect to the draft reports—as distinct from any email referrals—is discussed below.¹⁵

Privilege and work product claims denied with respect to the email referrals.

Exhibit 11

(BL123600093 BL123600123–BL123600147)

There are two parts to this Exhibit. The first part is an email from Ronald Fisher referring a draft report of the Fusarium Investigation Summary. The referral is to Suggy Chrai, some Bausch & Lomb personnel with a need to know, and also to inside and outside litigation counsel. The second part of the Exhibit is the attached draft report itself. Bausch & Lomb invokes privilege and work product for both the email referral and the exhibit.

The email itself is no more protected than the one considered in Exhibit 10. The entire email communication is the referral of the attachment for review. It makes no difference that attorneys are included on the email, because the mere fact of consultation is not protected by the privilege; and it is not work product.

The status of the draft reports attached to the email is far more complicated. The claims of privilege and work product, with respect to the draft reports, are taken in turn:

Attorney–Client Privilege:



As discussed above, Quantic was necessary to the legal representation after the FDA's inspection and the threat of litigation from both the FDA and private parties. Disclosure of the reports to Quantic for its review does not destroy the

privilege. But the reports are not completely protected by the attorney-client privilege in any case, because they are drafts of a final report that was intended to be (and was in fact) publicly disclosed to the FDA. The May 2008 ruling on draft reports, where the final is intended for public disclosure, controls here. That ruling provides as follows:


*12 “the portions of the draft [reviewed by counsel or a necessary agent] that were not disclosed in the final report may be redacted. The portions that were ultimately revealed to the FDA are not privileged. Defendant must therefore produce the draft, but may make redactions in accordance with this opinion and order.”

If, however, the draft reports are protected in their entirety as work product, then the work product ruling would render the privilege ruling moot.


Work Product:


As discussed above, the draft reports, in order to be protected under  CPLR 3101(c) or  (d), must be prepared solely in anticipation of litigation. Plaintiffs argue that the draft reports are not prepared solely in anticipation of litigation because Bausch & Lomb had an obligation, under Federal regulations, to submit a written report to the FDA of “any correction or removal of a device” if the correction or removal was initiated to reduce a health risk.¹⁶ Plaintiffs reason that because Defendant had a legal duty to file a report with the FDA, the Fusarium Investigation Summary could not have been prepared solely in anticipation of litigation as required for the work product protection under New York law.


Plaintiffs' argument has some appeal, but it does not give due consideration to Bausch & Lomb's legal situation at the time that the drafts were prepared. At that point, there was a serious risk of litigation by the FDA, and the actuality of litigation by private parties. There is no question that the Fusarium Investigation Summary, and the supporting reports, could be subject to admission on behalf of plaintiffs in a forthcoming lawsuit. It was therefore critical for Bausch & Lomb to comply with legal standards but to do so in a way that

did not expose it unnecessarily to evidence that could be used against it in litigation. It is common knowledge that reports made pursuant to legal obligations are not prepared in only one way. It is up to lawyers (and necessary consultants) to figure out how to comply with the reporting obligations and yet retain the optimal legal position for their client under the circumstances. That is why I find that the draft reports were prepared solely for purposes of litigation within the meaning of  [CPLR 3101](#).


I note that while the regulations relied upon by Plaintiffs required Bausch & Lomb to submit a report, it did not require the submission of *drafts* of that report. So in a real sense, the drafting process was solely directed toward litigation because the process was to write the report so as to comply with legal requirements and yet maximize a litigation position.




That said, the final report was of course submitted to the FDA. There was therefore a waiver of whatever work product protection existed with respect to the final report. See, e.g.,  [In re Steinhardt Partners, L.P.](#) 9 F.3d 230 (2nd Cir.1993) (voluntary disclosure of work product to a regulator investigating a possible violation waives the work product immunity, because the regulator is an adversary under the circumstances).¹⁷ The question then is whether a waiver of the final report operates to waive the work product protection as to the drafts. The better view, and the modern trend, is to hold that waiver by disclosure of a final document does not operate as a waiver of the drafts that are work product.

*13 The present state of the law on waiver of drafts, when the final product is waived by disclosure, is discussed in  [Randleman v. Fidelity Nat'l Title Ins. Co.](#), 251 F.R.D. 281, 285–6 (N.D. Ohio 2008)—a case involving draft affidavits prepared with the assistance of counsel, after the final affidavits had been disclosed to the adversary. The court held that the drafts retained work product protection. It analyzed the waiver question as follows:


The Southern District of Ohio, in  [Tuttle v. Tyco Electronics Installation Services](#), 2007 U.S. Dist. LEXIS 95527, 2007 WL 4561530, at *2 (S.D. Ohio) (Frost, J.), unambiguously stated that the work product doctrine protects information about the evolution of an affidavit from disclosure:

the work product doctrine does protect information relevant to the evolution of an affidavit, including



but not limited to communications with the counsel relating to the affidavit, prior drafts of the affidavit, and any notes made by counsel while engaging in the process of drafting the affidavit. See  [Infosystems, Inc. v. Ceridian Corp.](#), 197 F.R.D. [303] at 307, n. 4 [(E.D. Mich. 2000)]....





Although not controlling, recent cases have addressed this issue, and the trend is to consider draft affidavits and communications with counsel relating to affidavits as covered by the attorney work product doctrine. See, e.g.,  [Tuttle](#), *supra*, 2007 U.S. Dist. LEXIS 95527, 2007 WL 4561530, at *2;  [Kyoei Fire & Marine Ins. Co., Ltd. v. M/V Maritime Antalya](#), 248 F.R.D. 126, 155 (S.D.N.Y. 2007) (creating of affidavit subject to the “attorney work product privilege”);  [Ideal Elec. Co. v. Flowserve Corp.](#), 230 F.R.D. 603, 608–09 (D. Nev. 2005) (draft affidavits protected by the work product doctrine).

I find the reasoning of these courts persuasive and find that the draft affidavits and counsel correspondence are protected materials. * * *

Plaintiffs assert defendant waived the work product privilege by filing final versions of the affidavits to the court. They rely on *Infosystems* for their argument. In that case, the defendant had not produced the final affidavit it obtained from a non-party witness. The *Infosystems* court was concerned that the plaintiff would be unable to “test the perception and credibility” of the witness at his deposition unless the final affidavit was produced.  [Infosystems](#), *supra*, 197 F.R.D. at 307. * * * In *Infosystems* the court did not hold that the filing of a final affidavit waives the work product privilege as to draft affidavits or counsel communications. Rather, it held that if the defendant ultimately chose to make evidentiary use of a final affidavit which had not been produced to the plaintiff, the defendant would waive any work product claim as to that affidavit. In this case, plaintiffs have the final affidavits signed by the third-party witnesses and their need for the preliminary versions is less apparent.

This case differs from *Infosystems* in a significant way; Fidelity's filing of the affidavits with the court did not waive the work product doctrine's protection of earlier material.


*14 Similarly, in this case, Plaintiffs already have received the final Fusarium Investigation Summary and all of its supporting documents; and Defendant does not in any way appear to be using the Summary for its evidentiary benefit. The disclosure of the final version of the Summary and its supporting documents is separate and apart from the drafts, and accordingly does not waive the work product protection as to any drafts. See also  *Kyoei Fire & Marine Ins. Co., Ltd. v. M/V Maritime Antalya*, 248 F.R.D. 126, 155 (S.D.N.Y.2007) (drafts of an affidavit are work product even after a final draft is submitted, because the draft reflected “the mental processes and opinion of counsel”); *A.F.L. Falck, S.p.A. v. E.A. Karay Co.*, 131 F.R.D. 46, 49 (S.D.N.Y.1990) (holding that a draft affidavit “is properly work product in this litigation” and not ordinarily discoverable);  *Ideal Elec. Co. v. Flowserve Corp.*, 230 F.R.D. 603, 608–09 (D.Nev.2005) (holding that draft affidavits were protected by the work product immunity and rejecting the argument that “the inherent purpose of an affidavit to provide evidence from a witness belies any contention that the work product doctrine protects draft affidavits”).

The final question is whether Plaintiffs have made a showing sufficient to overcome the work product protection. First, if the draft reports are protected work product under  CPLR 3101(c), they are absolutely immune from production. As discussed above, however,  CPLR 3101(c) has been very narrowly construed, and appropriately so. While a case might be made that the drafts involve the mental impressions of attorneys sufficient to qualify the drafts under  CPLR 3101(c), I am reluctant to apply that provision given its questionable status in the New York case law. At any rate, I find it unnecessary to determine whether the drafts are absolutely protected under  CPLR 3101(c), because I find that Plaintiffs have not come close to establishing that they have “substantial need” for the drafts and are “unable without undue hardship to obtain the substantial equivalent of the materials by other means.”¹⁸

Plaintiffs submitted a 1 ½ page affidavit of Jerrold Parker, a member of the Plaintiff Steering Committee. He avers that he needs the draft reports, and cannot replicate their findings, because they “involve real time tests, performed on the subject product, the product container, and in many cases returned, used lenses and returned, used contact lens cases ...” What is not mentioned is that Plaintiffs received everything


that was submitted to the FDA—including the results of the real time tests. Plaintiffs thus have an alternative source of the information they seek—the final reports. See *Cline v. Advanced Medical Optics, Inc.* 2009 WL 585507 (E.D.Tex.), in which the court rejected a similar claim that work product immunity was overcome by the plaintiff’s need for root cause investigation materials:

[T]he Court is of the opinion that a significant portion of information relevant to the present litigation is already in the hands of the plaintiff. The defendants had previously made several reports related to the “root cause” investigation to the FDA as part of the recall of their allegedly defective product. Defendants have now made all of these reports available to the plaintiff.

*15 Accordingly, I find that the draft reports attached to the emails in Exhibit 11 are protected from disclosure under  CPLR 3101(d).

Attorney-client privilege claim denied (as to email communications) and mooted (as to draft reports). Work product claim rejected in part (as to email communications) and sustained (with respect to the attached reports).

Exhibit 12 (BL106686025–106686031)

This is another draft of a report that, in final form, became part of the package sent to the FDA. (Unlike Exhibit 11, there appears to be no email communication involved; the report is the entirety of the Exhibit). The draft report is therefore subject to the same treatment as the report in Exhibit 11. It is therefore exempt from disclosure under  CPLR 3101(d).¹⁹

Work product claim sustained. Privilege claim mooted.

Exhibit 13 (BL123599947)

Exhibit 13 is a single email, from Ronald Fisher to Bausch & Lomb personnel with a need to know, which simply refers the draft reports for review, and indicates how those reports may be reviewed. For reasons discussed above, this email is

not privileged and is not work product—it is simply a referral and therefore information about the fact of consultation—moreover, there are no lawyers copied on the email. The attachments are another question, but they are not included in Exhibit 13. As to the email itself, it must be produced.



Privilege and work product claims denied.


Exhibit 14 (BL122447088–BL122447089 BL123580077–BL123580078 BL123551258–BL123551259)

This is three versions of the same email from Ronald Fisher, essentially referring draft reports and seeking review from various Bausch & Lomb personnel, Quantic personnel, and attorneys. The communication is a bit more fulsome than previously considered emails that simply refer documents for review. Directions are given in the email that refer to the status of the drafts and various deadlines. But nothing in these directions involves any legal advice or confidential communications to counsel. And the directions are not material prepared in anticipation of litigation.²⁰

Privilege and work product claims denied.



Exhibit 15 (BL123599955–BL123599972 BL123600076–BL123600092 BL123599974–BL123599991)

These are all drafts of the Fusarium Investigation Summary. For reasons stated previously in the discussion of Exhibit 11, *supra*, these drafts are each protected as material prepared in anticipation of litigation under  CPLR 3101(d). The disclosure of the final report to the FDA does not waive the work product protection as to the drafts. And Plaintiffs have not made a sufficient showing of necessity and inaccessibility to overcome the qualified immunity provided by  CPLR 3101(d).

Bausch & Lomb also invokes the attorney-client privilege with respect to these draft reports. But that claim is mooted by the ruling on CPLR3101(d). As discussed above, the privilege does not protect the draft reports in their entirety—the reports could be redacted to delete any changes from the final that reflected advice of counsel. Under  CPLR 3101(d), in contrast, the draft reports are protected in their entirety.

***16** *Work product claim sustained. Privilege claim mooted.*

Exhibit 16 (BL000147293–BL000142794 BL107237871–BL107237890 BL106684972–BL106684991 BL144529915–BL133529934)

These are all drafts, or portions of drafts, of the Fusarium Investigation Summary. One of the draft reports (BL144529915–BL133529934) is blacklined for changes. The discussion under Exhibits 11 and 15 controls the result here. The drafts are each protected as material prepared in anticipation of litigation under  CPLR 3101(d). The privilege claims are mooted because the protection provided by the privilege is not as extensive as that provided by  CPLR 3101(d).

Work product claim sustained. Privilege claim mooted.

Order

Defendant must produce the following documents, with the limitations stated, within five days:

Exhibit 1 (BL000008073–BL000008085): This document must be produced, but Defendant may redact the information that is explicitly or implicitly derived from communications from Bausch & Lomb personnel. I have approved the redactions proposed by Defendant and therefore the document is to be produced in the form approved.

Exhibit 2 (BL106095385–BL106095388): The email dated June 15, 2006 (BL106095388) from an employee of Biss Lancaster, must be produced in unredacted form.

Exhibit 5 (BL120849169 BL120849170–BL120849180 BL120843003): Defendant must produce the challenged emails, but not the attachment.

Exhibit 6 (BL12851477–BL120851478 BL120851511–BL120851515):

The email from Lisa Tinsley, dated 8/14/2006, must be produced in unredacted form.

The email from Rao Gurijala, dated 8/15/2006, must be produced, but the first sentence may be redacted.

The email from David Hanlon, dated 8/18/2006, must be produced in unredacted form.

Exhibit 7 (BL 120849126): This email must be produced, but the third paragraph in the email may be redacted.

Exhibit 10 (BL123599710): The emails must be produced in unredacted form.

Exhibit 11 (BL123600093 BL123600123–BL123600147): The challenged email from Ronald Fisher must be produced in unredacted form. The attachment, however, need not be produced.

Exhibit 13 (BL123599947): The challenged email from Ronald Fisher must be produced in unredacted form.





Exhibit 14 (BL122447088–BL122447089 BL123580077–BL123580078 BL123551258–BL123551259): The challenged email from Ronald Fisher must be produced in unredacted form.


SO ORDERED:

All Citations

Not Reported in F.Supp.2d, 2009 WL 2842745

Footnotes

- 1 Panzica had previously prepared an audit report for Defendant, in August of 2002. This report has been disclosed to plaintiffs. Outside counsel reviewed that report and had additional questions, so Panzica was retained to do a follow-up audit report. It is that second report that is in contention here.
- 2 That argument is not made in Plaintiffs' brief, but it was made in previous correspondence to the Special Master from Daniel Burke, Esq.
- 3 Most of the case law involves accountants, as in *Kovel*, and patent agents. See, e.g.,  [Golden Trade, S.r.L. v. Lee Apparel Co.](#), 143 F.R.D. 514 (S.D.N.Y.1992) (statements to patent agent held within the privilege); Edward M. Spiro & Caroline Rule, 'Kovel' Experts Cloaked by Attorney–Client Privilege, N.Y.L.J., Feb. 22, 1994, at S1, S10 (privilege has been applied to “communications with a psychiatrist assisting a lawyer in forming a defense, a bail bondsman, and a polygraph operator”).
- 4 The same is true with another federal case cited by Defendant: [Cline v. Advanced Medical Optics, Inc.](#) 2009 WL 585507 (E.D.Tex.,2009), involved a “dual purpose” report—like the Panzica report.
- 5 The cases cited by Defendant on  [CPLR 3101\(c\)](#) are all ones in which the report of the consultant is prepared solely for purposes of litigation. For example, in the apparently leading case of *Santariga, supra*, the court held that a report prepared by a non-testifying expert radiologist fell within both 3101(c) and (d)—there was no purpose other than litigation for the report.
- 6 Bailey affidavit ¶ 21.
- 7 Id.
- 8 Bailey affidavit ¶ 25.
- 9 Bailey affidavit ¶ 34.
- 10 Because I find the attachment protected by the attorney-client privilege, there is no need to determine whether it is also protected material prepared in anticipation of litigation under  [CPLR 3101\(d\)](#). It should be noted, however, that the work product question is later taken up in detail with respect to other Quantic reports that are not completely protected by the attorney-client privilege. As will be seen, I find that those reports fall within the protections of  [CPLR 3101\(d\)](#), and that Plaintiffs have not made a showing of necessity that would overcome the qualified immunity. The work product analysis, as applied to those documents, should be equally applicable to the attachment that is part of Exhibit 5.
- 11 The reports referred to in the Tinsley email have been produced to Plaintiffs.
- 12 Because I find this paragraph protected by privilege, I need not decide whether it is protected as work product.

- 13 I therefore need not decide whether the redactions are justified under the work product doctrine.
- 14 I therefore need not decide whether the redactions are justified under the work product doctrine.
- 15 Defendant's motivation for invoking the privilege with respect to the email referral may be a concern that failing to object to production of the email could also be considered a waiver of any attached report. To clarify any concern. I am ordering production of the email, but deciding the issue of any attachment separately, as seen below. Under these circumstances, any ordered production of the email communication cannot constitute a waiver of any attached report. See *Hopson v. Mayor and City of Baltimore*, 232 F.R.D. 228 (D.Md.2005) (court-ordered production does not constitute waiver of privileged materials).
- 16 21 C.F.R. § 806.10, et seq. Defendant does not appear to contest Plaintiffs' contention that it had a legal duty, under the circumstances presented, to report to the FDA.
- 17 The final report submitted to the FDA has been produced to Plaintiffs.
- 18 Plaintiffs have the burden of showing substantial need and inaccessibility of equivalent materials.  *Lamite v. Emerson Elec. Co.—White Rogers Div.* 208 A.D.2d 1081, 617 N.Y.S.2d 924 (3d Dept.1994).
- 19 Defendant has also claimed privilege, but as discussed above, the privilege claim is essentially mooted because it provides only partial protection (for information not included in the final) whereas the work product doctrine protects the report in its entirety.
- 20 Again it appears that the claim of privilege and work product is made out of concern that production of the emails would constitute a waiver of privilege and work product with respect to the attachments. Assuming arguendo that a waiver as to reports could be found by production of the covering email, there can be no such concern when Bausch & Lomb is ordered to produce the email—as apart from the attached draft reports. See *Hopson v. Mayor and City of Baltimore*, 232 F.R.D. 228 (D.Md.2005) (court-ordered production does not constitute waiver of privileged materials).

End of Document

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